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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,709	08/22/2001	Charles A. Morris	1533.0520001	6249

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[REDACTED] EXAMINER

PULLIAM, AMY E

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1615

DATE MAILED: 02/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/933,709	MORRIS ET AL.
Examiner	Art Unit	
Amy E Pulliam	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 22 August 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 18-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 18-30 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

4) Interview Summary (PTO-413) Paper No(s) _____

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

Receipt is acknowledged of the Preliminary Amendment A, and the Information Disclosure Statement, received August 22, 2001, and November 1, 2001, respectively.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18, 19, 26, 27, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,486,435 to Schmidt *et al.*. Schmidt *et al.* teach a free-flowing, non-agglomerated, non-caking vitamin powder composition comprising about 45 to about 60 percent vitamin, about 2 to about 18 percent of a water insoluble carrier, about 0.2 to about 2 percent hydrophobic silica, and other ingredients (c 8, l 15-22). Schmidt *et al.* further teach that the water insoluble carrier can be corn starch (c 8, line 32). Schmidt *et al.* also teach that the vitamin can be selected from vitamin A, D, E, K and mixtures thereof, as well as vitamin B₁, B₆, B₂, B₁₂, C and mixtures thereof (c 2, l 20-34). Lastly, Schmidt *et al.* teach that the vitamin composition of their invention is suitable for the preparation of tablets (c 1, l 49).

Claims 26- 30 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,603,143 to Schmidt (US '143). US '143 discloses vitamin active powders which are more free-flowing and stable than conventional vitamin powders. US '143 teaches that the composition comprises at least one fat-soluble vitamin material and a silicon containing material (c 1, l 38-45). US '143 also teaches that the vitamin be vitamin E, and further explains that vitamin E comprises a group of natural substances known as tocopherols (c 2, l 55-57). It is the position of the examiner that this disclosure reads on applicant's claim to mixed tocopherols. Furthermore, US '143 teaches that the silicon dioxide used in their composition has a density of around 0.2 g/cc (which is equivalent to 12.5 lbs./cu. ft.), and a particle size which passes through a 100 mesh sieve (c 3-4, table 1). (A 100 mesh sieve allows only particles which are smaller than 150 microns to pass through).

Claims 18, 19, 26, 27, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,234,695 to Hobbs *et al.*. Hobbs *et al.* disclose a vitamin E composition comprising a free flowing powder containing a vitamin E compound, and at least one flow agent selected from silicon dioxide, starch and others (c 9, claims 1 and 2). Further, Hobbs *et al.* teach that the vitamin E compound is present in between about 20-60% (c 3, l 61).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 4,486,435 to Schmidt *et al.*. Schmidt *et al.* are discussed above as teaching a vitamin powder composition comprising silica, a vitamin, and corn starch.

Schmidt *et al.* do not teach that the vitamin is specifically mixed tocopherols. However, Schmidt *et al.* do teach that the vitamin can be selected from a group including vitamin E. Furthermore, applicant admits in his own specification that vitamin E is a mixture of different molecular species, including d-alpha, d-beta, d-gamma, and d-delta, which vary based on the natural variation of the oil (applicant's specification, p 3, 124-27). Therefore, it is the position of the examiner that based upon applicant's own admission, Schmidt's teaching of vitamin E suggests the limitations of the instant claims.

Schmidt *et al.* do not teach the specific density and surface area for the silica as claimed by applicant. However, it is the position of the examiner that with respect to the particular silica particle size, absent a clear showing of criticality, the determination and manipulation of particular sizes is within the skill of the ordinary worker as part of the process of normal optimization. The burden is shifted to applicant to show why the difference in particle size or surface area renders a different result.

One of ordinary skill in the art would have been motivated to make a vitamin composition comprising vitamin E, silica, and corn starch, based on the teachings of Schmidt. The expected result would be a free-flowing powder, non-sticking powder useful for pharmaceutical formulations. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 22-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 4,603,143 to Schmidt (US '143). US '143 is discussed above as teaching a composition comprising vitamin E and silica.

US '143 does not teach the specific particle size for the silica, as claimed by applicant. However, US '143 does teach that the particles are smaller than 150 microns. It is the position of the examiner that the determination of a particular particle sizes from within a broad range is within the skill of the ordinary worker as part of normal optimization. Additionally, US '143 does not teach the surface area of the silica. However, the burden is shifted to applicant to show that the silica disclosed by US '143 does not possess the same characteristics as the silica claimed by applicant. Lastly, US '143 does not specifically use the language mixed tocopherols in describing the vitamin to be used in their composition. However, as discussed in the anticipatory rejection, US '143 does teach that vitamin E is a group of natural substances known as tocopherol, and it further teaches that vitamin E can be used as the vitamin of the disclosed composition. Applicant admits in his own specification that vitamin E is a

mixture of different molecular species, including d-alpha, d-beta, d-gamma, and d-delta, which vary based on the natural variation of the oil (applicant's specification, p 3, l 24-27). Therefore, it is the position of the examiner that based upon applicant's own admission, the disclosure in US '143 teaching the use of vitamin E suggests the limitations of the instant claims. One of ordinary skill in the art would have been motivated to make a vitamin composition comprising vitamin E and silica. The expected result would be a free-flowing, fat-soluble vitamin powder with improved stability. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 18-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,234,695 to Hobbs *et al.*. Hobbs *et al.* are discussed above as teaching a vitamin E composition comprising a free flowing powder containing between 20-60% of a vitamin E compound and at least one flow agent selected from a group including silicon dioxide and starch.

Hobbs *et al.* do not teach that the vitamin is specifically mixed tocopherols. However, Hobbs *et al.* do teach that the vitamin can be selected from a group including vitamin E. Furthermore, applicant admits in his own specification that vitamin E is a mixture of different molecular species, including d-alpha, d-beta, d-gamma, and d-delta, which vary based on the natural variation of the oil (applicant's specification, p 3, l 24-27). Therefore, it is the position of the examiner that based upon applicant's own admission, Hobbs teaching of vitamin E suggests the limitations of the instant claims.

Hobbs *et al.* do not teach the specific density and surface area for the silica as claimed by applicant. However, it is the position of the examiner that with respect to the particular silica particle size, absent a clear showing of criticality, the determination and manipulation of particular sizes is within the skill of the ordinary worker as part of the process of normal optimization. The burden is shifted to applicant to show why the difference in particle size or surface area renders a different result.

One of ordinary skill in the art would have been motivated to make a vitamin composition comprising vitamin E, silica, and corn starch, based on the teachings of Hobbs *et al.*. The expected result would be a free-flowing powder, non-sticking powder useful for pharmaceutical formulations. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Art Unit: 1615

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

aep

February 13, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600